

CLAIMS

1. A hemodiafiltration apparatus capable of extracorporeal circulation operation in which extraction and reinfusion of blood are performed by using a single needle, that is, one puncture needle, comprising: a blood supply system for supplying blood; a dialysis fluid supply system for supplying a dialysis fluid; and a system for controlling movement of a fluid between the two supply systems, a blood circulation system having an arterial side blood circuit for extracting blood from a patient and flowing it into a hemodialyzer and a venous side blood circuit for returning blood from the hemodialyzer to the patient, at least one of the arterial side blood circuit and the venous side blood circuit of the blood circulation system having a blood pump which can control a flow rate and can turn in normal and opposite directions, the dialysis fluid supply system having a dialysis fluid supply line for perfusing the hemodialyzer with a dialysis fluid and a dialysis fluid discharge line, at least one of the two blood circuits of the blood circulation system having a blood pump which can control the flow rate and can turn in normal and opposite directions, the dialysis fluid supply line and the dialysis fluid discharge line having delivery means for supplying a dialysis fluid and delivery means for discharging a dialysis fluid, respectively, one of the dialysis fluid supply line and the dialysis fluid discharge line having at least one filtration/back-filtration fluid supply means

for carrying out filtration and back-filtration together with the delivery means, which can turn in normal and opposite directions and can control a flow rate, and at least one water removing and fluid discharge means, and having a mechanism for extracting blood into the blood circuit by flowing out a fluid in the blood circuit to a dialysis fluid circuit side by filtration through a hemodialyzer accommodating a hollow yarn membrane and a mechanism for returning the blood in the blood circuit to the patient by flowing the dialysis fluid from the dialysis fluid circuit side to the blood circuit side by forced back-filtration through the hemodialyzer, characterized in that:

the hemodiafiltration apparatus includes a mechanism capable of repeating intermittently and at least a plurality of times an operation of flowing out a fluid from the blood circuit side to the dialysis fluid circuit side by filtration (hereinafter also referred to as "filtration" or "blood extraction") and the operation of flowing the fluid into the blood circuit side from the dialysis fluid side by back-filtration (also referred to as "back-filtration" or "reinfusion").

2. A hemodiafiltration apparatus according to claim 1, comprising: a blood circuit for a single needle having a Y-shaped or T-shaped junction portion with a puncture needle; and two branch circuits branching off from the junction portion (a branch on an upstream

side of a hemodialyzer and a branch on a downstream side of the hemodialyzer during the circulation of blood are called "branch on an arterial side" and "branch on a venous side", respectively), wherein a blood circuit having a pump segment for mounting a blood pump to one of the two branch circuits is used to enable hemodiafiltration with a single needle.

3. A hemodiafiltration apparatus according to claim 1 or 2, wherein the filtration operation (filtration phase) and the back-filtration operation (back-filtration phase) are automatically repeated alternately.

4. A hemodiafiltration apparatus according to any one of claims 1 to 3, wherein a blank time (blank phase) having an arbitrary length during which neither filtration operation nor back-filtration operation is carried out is interposed between the filtration operation and the back-filtration operation or between the back-filtration operation and the filtration operation.

5. A hemodiafiltration apparatus according to any one of claims 1 to 4, wherein a step of carrying out blood circulation in the blood circuit in the blank phase having an arbitrary length during which neither filtration operation nor back-filtration operation is carried out is interposed between the filtration operation and

the back-filtration operation or between the back-filtration operation and the filtration operation to repeat the operation automatically.

6. A hemodiafiltration apparatus according to any one of claims 1 to 5, characterized in that the blood of the patient is extracted into a blood circuit of one branch by making a fluid supply rate from the patient side to the hemodialyzer side of the blood pump provided in at least one of the blood circuits and a filtration rate through the hemodialyzer equal to each other in the filtration operation.

7. A hemodiafiltration apparatus according to any one of claims 1 to 5, characterized in that the blood pump provided in at least one of the blood circuits is stopped and the blood of the patient is extracted into the blood circuit of one branch by filtration through the hemodialyzer in the filtration operation.

8. A hemodiafiltration apparatus according to any one of claims 1 to 7, characterized in that the blood in the blood circuit of one branch is returned to the patient by making the fluid supply rate from the hemodialyzer side to the patient side of the blood pump provided in at least one of the blood circuits and a back-filtration rate through the hemodialyzer equal to each other

in the back-filtration operation.

9. A hemodiafiltration apparatus according to any one of claims 1 to 7, characterized in that the blood pump provided in at least one of the blood circuits is stopped and the blood in the blood circuit of one branch is returned to the patient side by the back-filtration through the hemodialyzer in the back-filtration operation.

10. A hemodiafiltration apparatus according to any one of claims 1 to 9, characterized in that the blood of the patient is extracted into the blood circuit through the venous side and the arterial side of the blood circuit based on the ratio of the fluid supply rate from the patient side to the hemodialyzer side of the blood pump provided in at least one of the blood circuits to the filtration rate through the hemodialyzer in the filtration operation.

11. A hemodiafiltration apparatus according to any one of claims 1 to 10, characterized in that the blood of the patient is extracted into one branch extending toward the hemodialyzer side of the blood pump provided in at least one of the blood circuits from a single needle based on the ratio of the fluid supply rate from the patient side to the hemodialyzer side of the blood pump provided in at least one of the blood circuits to the filtration rate through the

hemodialyzer in the filtration operation, and the amount of the blood corresponding to the difference between the rate of the blood pump and the filtration rate is re-circulated from one branch side where no blood pump is provided to the branch side where the blood pump is provided.

12. A hemodiafiltration apparatus according to any one of claims 1 to 11, characterized in that all or a part of the blood in the blood circuit is returned to the patient side through the venous side and the arterial side of the blood circuit based on the ratio of the fluid supply rate from the hemodialyzer side to the patient side of the blood pump provide in at least one of the blood circuits to the back-filtration rate through the hemodialyzer in the back-filtration operation.

13. A hemodiafiltration apparatus according to any one of claims 1 to 12, characterized in that the blood in the blood circuit is supplied from one branch side where the blood pump is not provided of the blood circuit to the junction portion of the two branch circuits based on the sum of the fluid supply rate from the patient side to the hemodialyzer side of the blood pump provided in at least one of the blood circuits and the back-filtration rate through the hemodialyzer, and the blood is re-circulated from one branch side where the blood pump is not provided to the other branch side where

the blood pump is provided at a rate of the blood pump while the blood is returned to the patient side at a back-filtration rate with a single needle through the junction portion of the two branch circuits.

14. A hemodiafiltration apparatus according to any one of claims 1 to 13, wherein a water removing step and a dialyzing step (the perfusion of the hemodialyzer with a dialysis fluid) are provided in the blank phase, that is, between the filtration operation and the back-filtration operation or between the back-filtration operation and the filtration operation while the blood in the blood circuit is circulated.

15. A hemodiafiltration apparatus according to any one of claims 1 to 14, wherein the water removing step is carried out by activating the water removing and fluid discharge means in one or more of the filtration phase, back-filtration phase and blank phase set in an arbitrary ratio independently of the filtration/back-filtration fluid supply means.

16. A hemodiafiltration apparatus according to any one of claims 1 to 15, the water removing step comprises a step of maintaining an inside volume of the circuit constant by extracting the blood in an amount equal to an amount of the removed fluid from the patient

side in.

17. A hemodiafiltration apparatus according to any one of claims 1 to 16, wherein an amount of movement of the fluid by each operation (amount of filtrate or amount of reverse filtrate) is calculated from the product of a moving rate of the fluid by each operation (filtration rate or back-filtration rate) and a time required for each operation.

18. A hemodiafiltration apparatus according to any one of claims 1 to 17, wherein when a minimum recurring unit composed of a combination of an arbitrary numbers and the order of a series of filtration phases, back-filtration phases and blank phases is taken as one cycle, a time of the back-filtration operation in each cycle is set shorter than a time of the filtration operation in the same cycle, and the back-filtration rate in each cycle is set higher than the filtration rate in the same cycle.

19. A hemodiafiltration apparatus according to any one of claims 1 to 18, wherein when a total time required for an entire hemodiafiltration step is taken as working time, the number of cycles which are carried in the working time can be set to any value.

20. The hemodiafiltration apparatus according to any one of claims

1 to 19, wherein when the amount of the body fluid removed to correct an excess of the body fluid of the patient is taken as the amount of the removed water, a total amount of a reverse filtrate flown by the back-filtration operation as a total amount of a substitution fluid (equal to a total amount of a filtrate flown out by the filtration operation) and the number of cycles, each composed of at least the filtration operation and the back-filtration operation, as the number of cycles in the hemodiafiltration step over the working time, the hemodiafiltration step with a single needle is manipulated or controlled over the working time by setting at a beginning of the hemodiafiltration step the working time, the amount of the removed water, the amount of the substitution fluid and the number of cycles.

21. A hemodiafiltration apparatus according to any one of claims 1 to 20, wherein the hemodiafiltration step performed by using a single needle is manipulated or controlled by inputting the amount of the removed water and the total amount of the substitution fluid.

22. A hemodiafiltration apparatus according to any one of claims 1 to 21, wherein when there is no input of the working time or the number of cycles, the hemodiafiltration step is manipulated or controlled with an initial value set into an input unit.

23. A hemodiafiltration apparatus according to any one of claims 1 to 22, characterized by comprising a mechanism which enables the filtration/back-filtration rates and the times of the filtration phase, the back-filtration phase and the blank phase to be set to any values by means of one fluid supply means which can turn in normal and opposite directions (hereinafter also referred to as "polyfunctional filtration control means") in place of at least one filtration/back-filtration fluid supply means and at least one water removing and fluid discharge means in the hemodiafiltration apparatus according to claim 1.

24. A hemodiafiltration apparatus according to any one of claims 1 to 23, wherein when the amount of a fluid discharged from the dialysis fluid circuit by polyfunctional filtration control means independently of delivery means for discharging a dialysis fluid is taken as the amount of a fluid discharged by a pump, the filtration/back-filtration rate per cycle or per working time of the polyfunctional filtration control means is adjusted so that the amount of the fluid discharged by the pump becomes the sum of the amount of removed water flown out from the blood side circuit to the dialysis fluid side circuit by the water removing step and the amount of the substitution fluid flown from the dialysis fluid side circuit into the blood circuit by the back-filtration operation.

25. A hemodiafiltration apparatus according to any one of claims 1 to 24, wherein the amount of the fluid discharged by the pump in each cycle is regulated such that the amount of the fluid discharged by the pump in each cycle becomes the total of the amount of the removed water and the amount of the substitution fluid in each cycle.

26. A hemodiafiltration apparatus according to any one of claims 1 to 25, wherein the amount of water removed per cycle is programmed such that when the amount of water removed by the filtration operation in each cycle is taken as the amount of the removed water (from the patient) per cycle, the amount of the removed water per cycle becomes a value obtained by dividing the amount of water removed from the patient by the number of cycles or a time function.

27. A hemodiafiltration apparatus according to any one of claims 1 to 26, wherein when the amount of blood filtrated by the filtration operation in each cycle is taken as the amount of filtration per cycle, the amount of filtration per cycle is calculated as the product of the back-filtration rate and the back-filtration time apportioned to each cycle (the sum of the products when there are a plurality of back-filtration phases in one cycle).

28. A hemodiafiltration apparatus according to any one of claims

1 to 27, wherein when a time required for the filtration operation in each cycle is taken as the filtration time per cycle (the time of the filtration phase), an amount of a fluid discharged by the filtration/back-filtration fluid supply means and the water removing and fluid discharge means or the polyfunctional filtration control means in the same filtration operation as the amount of the fluid discharged by the pump per cycle, a time required for the back-filtration operation in each cycle as the time of the back-filtration phase per cycle, and an amount of a fluid flown in by the back-filtration operation as the amount of the substitution fluid per cycle, the filtration time per cycle, the amount of filtration per cycle and the amount of the fluid discharged by the pump per cycle are automatically set by changing the time of the back-filtration phase per cycle.

29. A hemodiafiltration apparatus according to any one of claims 1 to 28, wherein the time of the back-filtration phase per cycle, the amount of the substitution fluid per cycle and the amount of the fluid discharged by the pump per cycle are automatically set by changing the time of the filtration phase per cycle.

30. A hemodiafiltration apparatus according to any one of claims 1 to 29, wherein the amount of the substitution fluid per cycle or the amount of the removed water per cycle can be altered by

changing the amount of the substitution fluid per cycle or the amount of filtration per cycle.

31. A hemodiafiltration apparatus according to any one of claims 1 to 30, wherein the time required for each cycle can be changed arbitrarily in each cycle.

32. A hemodiafiltration apparatus according to any one of claims 1 to 31, wherein when a filtration/back-filtration pattern per cycle is composed of time apportionment to the filtration phase, the back-filtration phase and the blank phase per cycle and settings for the amount of filtration, the amount of the substitution fluid and the water removal rate or amount, if the filtration/back-filtration pattern per cycle is initialized or changed, the filtration/back-filtration pattern for cycles after the set cycle is set to be the same or is changed.

33. A hemodiafiltration apparatus according to any one of claims 1 to 32, wherein the set water removing conditions and the filtration/back-filtration pattern for each cycle can be automatically changed by feed-back control from measuring means for measuring the hematocrit value, the amount of the circulating blood, and the blood pressure.

34. A hemodiafiltration apparatus according to any one of claims 1 to 33, wherein the filtration/filtration pattern of each cycle can be changed to attain a water removing rate set by an ultrafiltration water removing program for changing the water removing rate according to the preset time dependence.

35. A hemodiafiltration apparatus according to any one of claims 1 to 34, wherein the cycle is composed of one or more filtration phases, one or more back-filtration phases and the number and the order of 0, one or more blank phases, and the cycle is repeated at least two times in the working time.

36. A hemodiafiltration apparatus according to any one of claims 1 to 35, wherein the amount of movement of the fluid (the amount of a filtrate or the amount of a reverse filtrate) in each operation for a given time is calculated from the product (or the sum of the products for the given time) of the fluid moving rate of each operation (filtration rate or back-filtration rate) and the time required for each operation (the time of the filtration phase or the back-filtration phase).